

K052696

510 (k) Notification

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing  
Covalon Technologies Ltd.

FEB 3 2006

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**510 (k) Summary**

OWNERS NAME: COVALON TECHNOLOGIES LTD.

ADDRESS : 405 BRITANNIA ROAD EAST, SUITE 106  
MISSISSAUGA, ONTARIO, CANADA L4Z 3E6

CONTACT PERSON: ROBERT B. MILLER MD. FRCS(C), FACS  
DIRECTOR OF CLINICAL AND REGULATORY  
AFFAIRS

PHONE : (905) 568-8400

FAX: (905) 568-5200

DATE OF PREPARATION: SEPTEMBER 25, 2005

NAME OF DEVICE: **CovaClearAg™** COLLAGEN WITH SILVER,  
ANTIMICROBIAL GEL SHEET DRESSING

COMMON NAME: WOUND DRESSING

CLASSIFICATION NAME: WOUND DRESSING (21 CFR 807.87  
PRODUCT CODE FRO)

SUBSTANTIAL  
EQUIVALENCE: ColActiveAg™ Collagen with Silver Antimicrobial  
Wound Dressing (k043296)

SilvaSorb® Silver Antimicrobial Dressing (k002599)

**DEVICE DESCRIPTION:** CovaClearAg™ Collagen with Silver, Antimicrobial, Gel Sheet Dressing is an advanced wound care dressing composed of collagen and silver lactate provided in a sterile sheet. CovaClearAg™ Collagen with Silver, Antimicrobial Dressings are pliable, hydrated collagen sheets that maintain a moist environment at the wound surface that aids in the formation of granulation tissue and epithelialization. Because of its significant water content (77.5%), the dressing provides hydration to the wound surface.

The dressings act as an effective barrier to bacterial and fungal penetration. The silver content is intended to prevent colonization of the dressing. The dressings can be cut to fit specific wounds and can be layered for the management of deep wounds.

**INTENDED USE:** CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing is indicated for the management of full and partial thickness wounds including:

Pressure ulcers, Diabetic ulcers, Ulcers caused by mixed vascular etiologies, Venous ulcers, Donor and Graft sites, Abrasions and lacerations, Traumatic wounds healing by secondary intention, Dehisced surgical wounds, First & Second degree burns.

**Precautions:**

If sensitivity to the product develops, discontinue use. CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing may be used under compression therapy under the supervision of a health care professional.

**Contraindications:**

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressings should not be used on patients with a known allergy or sensitivity to porcine collagen, to silver or on third degree burns.

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*Warning: This device, when used in preclinical animal testing (in vitro testing) has demonstrated a hemolytic activity above the normal levels. This device is intended for topical use only and should not be used in deeper wounds beyond the Indications for Use statement.*

*(Amendment for x dated January 24, 2006 - DXV)*

### Technological Characteristics of Device:

## COMPARATIVE TABLE

CovaClearAg™ Collagen with Silver Antimicrobial Gel Sheet Dressing

ColActive Ag™ Collagen with Silver, Antimicrobial Dressing

SilvaSorb® Silver Antimicrobial Wound Dressing

<b>Product Name</b>	CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing	ColActiveAg™ Collagen With Silver Antimicrobial Dressing	SilvaSorb®, Silver Antimicrobial Dressing
<b>Manufacturer</b>	Covalon Technologies Ltd.	Covalon Technologies Ltd.	AcryMed, Inc
<b>Regulatory status</b>	Subject of this 510(k)	K043296	K002599
<b>Materials of Construction</b>	Collagen Silver Lactate Silver Chloride	Collagen ,Alginate Silver Lactate Silver Chloride	Polyacrylate, Silver Chloride
<b>Sterility</b>	Sterile	Sterile	Sterile
<b>Comparable Sizes</b>	Yes	Yes	Yes
<b>Biocompatibility Testing</b>	Yes	Yes	Yes
<b>Intended Use</b>	Pressure, venous, diabetic, Vascular ulcers, 1 <sup>st</sup> & 2 <sup>nd</sup> degree burns, various surgical & traumatic wounds	Pressure, venous, diabetic, vascular ulcers, 1 <sup>st</sup> & 2 <sup>nd</sup> degree burns, various surgical & traumatic wounds	Pressure, venous, diabetic, vascular ulcers, 1 <sup>st</sup> & 2 <sup>nd</sup> degree burns, various surgical & traumatic wounds
<b>Antimicrobial Effect</b>	Yes	Yes	Yes

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## **Safety & Efficacy Evaluation**

### **Biocompatibility Testing:**

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing has been tested for biocompatibility as outlined in the General Program Memorandum - #G95-1, Office of Device Evaluation entitled "Use of International Standard ISO - 10993 - "Biological Evaluations of Medical Devices Part 1: Evaluation and Testing". These were performed on our finished packaged device that has undergone a validated sterilization process.

We believe that this position is consistent with that set down in FDA Document 'Draft Guidance for the Preparation of a Pre-market Notification for a Non-Interactive Wound and Burn Dressing', Second Revision - November 26, 1997. **Attachment I** contains a testing schedule of all biocompatibility tests conducted that demonstrate that CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing is biocompatible, along with all test results.

CovaClear Ag™ Collagen with Silver, Antimicrobial Gel Sheet Dressing is made from the same Gelatin as its predicate ColActive Ag™. In the 510(k) filing for ColActiveAg™, the FDA was concerned regarding the inactivation of Porcine Parvo Virus (PPV) and Swine Influenza Virus (SIV) in the gelatin manufacturing process or through the sterilization process of the final device. For that 510(k) filing, Covalon conducted a review of the manufacturing process of the raw material as well as the sterilization process and how it affects the PPV and SIV, and included an extensive literature review to support the inactivation of the two aforementioned viruses. The data provided demonstrated the inactivation of both viruses and consequently the safety of the raw material. **(Attachment XII)**

### **CONCLUSIONS:**

It has been shown that CovaClearAg™ is comparable in composition with the predicate devices and shows substantial equivalence. The Biocompatibility testing shows safety of the product. Results of the Kirby-Bauer testing shows the product functions with respect to its antimicrobial claims.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert B. Miller, M.D., FRCS(C), FACS  
Director of Clinical and Regulatory Affairs  
Covalon Technologies Ltd.  
405 Britannia Road East, Suite 106  
Mississauga, Ontario L4Z 3E6  
CANADA

Re: K052696

Trade/Device Name: CovaClearAg™ Collagen with Silver Antimicrobial Gel Sheet  
Dressing

Regulatory Class: Unclassified

Product Code: FRO

Dated: January 13, 2006

Received: January 17, 2006

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

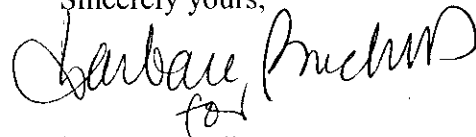
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a small "for" written below it.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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**Indications for Use**

510(k) Number: K052696

Device Name: CovaClearAg™ Collagen with Silver Antimicrobial Gel Sheet Dressing

Indications for Use: CovaClearAg™ Collagen with Silver, Antimicrobial Gel Sheet

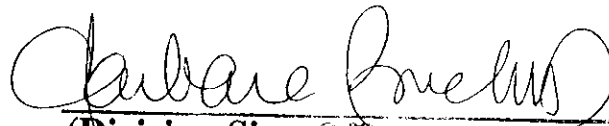
Dressing is indicated for the management of full and partial thickness wounds including:

- pressure ulcers
- diabetic ulcers
- ulcers caused by mixed vascular etiologies
- venous ulcers
- donor and graft sites
- abrasions and lacerations
- traumatic wounds healing by secondary intention
- dehisced surgical wounds
- first and second degree burns

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)



(Division Sign Off)

Division of General Restorative,  
and Neurological Devices

510(k) Number K052696